AD		
	(Leave b	olank)

AWARD NUMBER: W81XWH-11-2-0178

TITLE: ARCPEP 2 -SHUPEP

PRINCIPAL INVESTIGATOR: COL (Ret) Marina N. Vernalis Janice Sandrick, Ph.D.

CONTRACTING ORGANIZATION:

Henry M. Jackson Foundation for the Advancement of Military Medicine Rockville, MD 20852-1402

REPORT DATE: October 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research æ) å ÁT æe^ læ |ÂÔ[{ æ) å Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

Form Approved REPORT DOCUMENTATION PAGE OMB No. 0704-0188 Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS. 1. REPORT DATE (DD-MM-YYYY) 2. REPORT TYPE 3. DATES COVERED (From - To) 9/26/11-26/09/12 26 October **ANNUAL** 4. TITLE AND SUBTITLE 5a. CONTRACT NUMBER ARCPEP 2 - SHUPEP W81XWH-11-2-0178 5c. PROGRAM ELEMENT NUMBER 6. AUTHOR(S) 5d. PROJECT NUMBER COL(Ret) Marina Vernalis, DO, FACC 5e. TASK NUMBER Janice Sandrick, Ph.D. 5f. WORK UNIT NUMBER email: marnia.vernalis@med.navy.mil 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION REPORT NUMBER The Henry M. Jackson Foundation For the Advancement of Military Medicine, Inc. Rockville, MD 20852 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSOR/MONITOR'S ACRONYM(S) US Army Medical Research **Acquisition Activity** 11. SPONSOR/MONITOR'S REPORT Fort Detrick, Maryland 21702-5012 NUMBER(S) 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved of Public Release statement: distribution unlimited. 13. SUPPLEMENTARY NOTES 14. ABSTRACT It is widely acknowledged that cardiovascular disease prevention requires intervention as early in the human lifespan as practical A window of opportunity presents in early adulthood when students gain independence as young adults attending university. In three-phase investigation, this study will evaluate the behavioral patterns of university students in the domains of diet, exercise, stress management, smoking and sleep (phase 1). Informed with information from phase 1, a pilot study (phase 2) will test the feasibility of performing an intervention in university students consisting of an 8-week period during which the students will receiv three text messages (by phone or iPad) per week, tailored to address the behavioral issues that the student has identified as needing improvement and for which the student has indicated a desire to make change. Using lessons learned in phase 2, a randomized, controlled trial of the 8 week intervention (phase 3) will be performed with the plan to compare the outcomes of behavior change, measures of anthropomorphic data, and serum markers of cardiovascular risk to test the impact of the intervention.

Lifestyle; Cardiac Prevention; Behavior; Coronary Heart Disease (CHD); Metabolic Syndrome; Cardiovascular Disease (CVD);

17. LIMITATION

OF ABSTRACT

18. NUMBER

6

OF PAGES

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:

b. ABSTRACT

c. THIS PAGE

ΤŢ

Obesity; Stress

a. REPORT

Standard Form 298 (Rev. 8-98) Prescribed by ANSI Std. Z39.18

19a. NAME OF RESPONSIBLE PERSON

19b. TELEPHONE NUMBER (include area

USAMRMC

code)

Table of Contents

	<u>Page</u>
Executive Summary	4
Introduction	4
Key Research Accomplishments	6
Reportable Outcomes	6
Conclusion	6

Executive Summary ARCPEP 2: Seton Hill University Personal Empowerment Project (SHU-PEP) Annual Report

Dates: 3/21/12-26/09/12

Utilizing a three phase project, the purpose of this research is to assess the lifestyle habits of college students attending a midsized university and, armed with this information, to develop and implement an intervention to improve lifestyle choices. In keeping with this aim, collaborative research efforts have continued between ICHP projects at Walter Reed National Military Medical Center and Seton Hill University.

To date all Seton Hill University project staff have been hired, equipment purchased. renovations completed and the recruitment strategy has been finalized. At Walter Reed National Military Medical Center the vendor has been selected, contracted and the kickoff meeting has occurred to develop the web based health survey tool and coaching platform. This tool will be used to determine the proportion of young adults attending college who engage in unhealthy behaviors with regard to diet habits and choices, exercise practices, levels of perceived stress and stress management choices, smoking and sleep habits. This tool will also be used to investigate preferred modes of communication (e.g. telephonic messages, text messages, iPad messages) for effective delivery of health information to these young adults. There have been numerous collaborative emails, conference calls and site visits by each site. The SHU-PEP team hosted a kick-off meeting at Seton Hill University attended by Audra Nixon, WRNMMC Program Manager for the project and staff from Henry Jackson Foundation, Regulatory Affairs. The WRNMMC team conducted a Health Engagement Coaching Workshop at Walter Reed for the entire SHU-PEP team and select students from the Nutrition Department. The project is on target to begin recruitment this winter on campus and finalized the Phase 1 recruitment by May 2013.

Introduction:

This study aims to study the issues of health behaviors in the domains of nutrition, exercise, stress, sleep and smoking. We aim to improve health behaviors in these domains by evaluating lifestyle choices, learning styles, and communication preferences with a three-phase investigation.

Phase I has the specific objective of lifestyle assessment. Phase 2 constitutes a pilot study in a limited number of university students to determine the feasibility of causing healthy behavior change by health coaching and the use of electronic messaging to university students. Phase 3 will measure improvements in the lifestyle behaviors of students as a result of health coaching and electronic feedback messages.

Body:

The following deliverable was completed in April, 2012: **Protocol approval by Seton Hill University IRB**

In addition, the following tasks were completed at Seton Hill: (March 21-June 15)

- Reviewed subaward agreement and prepared for conference call with HJF
- Worked on research proposal with ICHP colleagues
- Participated in conference call with HJF colleagues on March 29, 2012

- Developed Demographic Questionnaire for use in research
- Submitted proposal and consent forms to SHU IRB
- Responded to SHU IRB questions and revised forms as necessary
- Received Seton Hill IRB approval
- Continued collaboration with ICHP colleagues
- Developed summer plan of work
- Scheduled HJF meeting for July
- Investigated equipment supplies and purchased the following: digital stadiometers, body circumference and girth measuring tapes, digital blood pressure monitors and stands, scales with carrying cases, bioimpedance devices and electrodes and Bod Pod with computer cart and breathing tubes/filter kits
- Discussed marketing ideas and SHU-PEP logos with marketing team
- Reviewed areas to be used for research space and met with Maintenance concerning renovation
- Began renovation of research space. Materials were purchased, and renovations are expected to be complete and space functional by August 1, 2012.
- Met with SHU Instructional Designer and Admissions
- Investigated sources of public domain pictures
- Developed ads for Clinical Research Coordinator and Health Coaches
- Obtained approval for ads and submitted to online sources
- Reviewed initial resumes received
- Reviewed Health Coach System User Requirements document and discussed questions with A. Nixon and scientific team

The following tasks were completed at Seton Hill (June 16 – Sept 26)

- Reviewed all materials supplied by applicants for the Clinical Research Coordinator and Health Coach positions
- Conducted telephone and in-person interviews with viable Clinical Research Coordinator and Health Coach candidates
- Hosted meeting at Seton Hill with HJF colleagues on July 24, 2012
- Hired Clinical Research Coordinator and one Health Coach
- Investigated and ordered the following equipment: office equipment, exam tables, phlebotomy chairs, MAC books, iPads, multi-function copier device, bathing suits for use in BodPod, and BodySense Wear
- Monitored delivery of equipment
- Reviewed DoD language added to protocol and informed consents by HJF colleagues
- Met with IRB chair and Director of Grants and Government Support concerning information needed to comply with DoD language
- Oriented CRC and Health Coach to position/department/university
- New hires completed the following:
 - High-level review of all research materials (protocol, informed consents, etc)

Developed and conducted three hour SHU PEP research training workshop for SHU dietetics students who will participate in research

Created SHU PEP research manuals for research training workshop

Received and set- up lab equipment

Created inventory list for equipment

Numbered Sensewear, created sign-in/out sheet for issuing devices

Created schedule, timeline, & check sheet for each participant for data collection

Took each survey back to back and estimated time needed

Created order of data collection component

Created template for appointment reminder cards

Ordered rolling carts, temp/humidity display, other misc. items

Tested equipment and created step-by-step instructions sheets for Blood pressure

Sensewear /Actigraph

Bioimpedence

BodPod

Stadiometer

Waist, neck circumference

Set-up Bayley 208 and decided on dressing area placement in Bayley 206

Planned student workshop to train on all equipment

Mapped out recruitment strategies

Conducted brainstorming on recruitment materials

Followed up with equipment orders, continuing to research specifics for items need, submitting paperwork, etc.

- Met with student coordinating Open House event
- Participated in BodPod training conducted by CosMed Representative
- Met with BodPod repairperson, reviewed repair work, discussed need for new handle and touch ups.
- Tested all data collection equipment
- Met with SHU graphic designer regarding project logos
- Organized trip to Walter Reed
- Participated in Health Engagement Coaching Workshop conducted by ICHP colleagues at Walter Reed
- Developed poster on results of pilot testing of Rate Your Plate survey accepted for presentation at the Academy of Nutrition and Dietetics Food and Nutrition Conference and Exhibition
- Completed or in the process of completing CITI HIPAA online training course

Key Research Accomplishment: None to report to date.

Reportable Outcomes: None to report to date.

Conclusions: Research phase not yet begun; therefore, no results or conclusions to report.